

*IN THE ABSTRACT:*

Add the following Abstract of the Disclosure:

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ABSTRACT OF THE DISCLOSURE

16 The invention relates to an improved bone screw for use in orthopaedic surgery, in particular with external fracture fixation devices, of the type which comprises ahead (3), a shank (4), and a threaded portion (5) tapering towards a tip (2) at the opposite end from the head (3). Advantageously, the threaded portion (5) has at least one constant pitch section comprising threads (9) which have a triangular cusp-like profile in cross section and are separated from each other by a shaped bottom land with a concave profile (10) defined by two countersloping planes.

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REMARKS

The specification and claims have been carefully reviewed in the light of the Office Action to which this amendment is responsive. By this amendment, claim 1 has been canceled without prejudice, and in place thereof, new claim 11 is submitted which is believed to have improved form and distinguishes even more clearly over the prior art. Corresponding amendments have been made to the specification, consistent with the original disclosure, so as not to involve new matter. An Abstract of the Disclosure is being submitted, consistent with the abstract included with the published PCT application.

Claims 1-10 have been rejected as being obvious over Gustilo (4,463,753) in view of Grossberndt (4,544,313) and reconsideration of such rejection is respectfully requested. Applicant has disclosed and claimed herein an orthopaedic surgery bone screw, particularly adapted for use in external fixture fixation devices. As brought out in the specification, the bone screw has a thread profile which optimizes bone stress transfer which enhances bone material relaxation into the concave root lands of the threads. More particularly, the bone screw has a threaded portion having an outside diameter and a core diameter which tapers towards the screw tip, with the generally triangular threads of the threaded portion (1) being separated by a bottom land having a concave profile defined by

two countersloping planes, and (2) having a constant height with the ratio of the outside diameter to the core diameter of the threads being within a range of 1.43 to 1.60. The thread profile and arrangement has unexpectedly been found to create surfaces that allow material that is being removed to slide during penetration of threads, thus relieving the bone stress.

In contrast, while Gustilo discloses a bone screw with a tapered threaded section, it lacks any appreciation of the important features of applicant's invention. Nor does Grossberndt provide any teaching which would enable a person skilled in the art to modify Gustilo. Grossberndt discloses threads the height of which reduce continually toward the end 3 of the screw (see col. 2, ll. 47-50) and have a ratio between the outside diameter and the core diameter of approximately 1.85 (see claim 1).

The prior art, furthermore, lacks any appreciation for the problem, or the solution, to which applicant's invention is directed. Indeed, applicant has ascertained that regrowth of the bone in the several zones between the teeth can only be effectively achieved if the effective height of the uniformly shaped teeth reduces by virtue of the taper. The self-tapping profile of the screw according to the present invention enables removal of bone shavings and the compacting thereof in a manner that stimulates growth and the enhanced distribution of pressure over the contact surfaces. Grossberndt, on the other hand, teaches threads of unequal height, having relatively thin and high profiles (see col. 2, l. 42) with a relatively large pitch and a large ratio between the outside diameter and the core diameter (see col. 1, ll. 8-10) which would not optimize bone stress and enhance desired bone regrowth. Hence, neither Gustilo nor Grossberndt provide any disclosure or suggestion of the invention as set forth in independent claim 11 as now presented. Since the remaining claims all are dependent upon claim 11, they similarly are believed to distinguish over the prior art.

In re Appln. of Venturini  
Application No. 09/937,941

From the foregoing, it is believed that the claims as now presented all patentably distinguish over the prior art so as to be in condition for allowance. Accordingly, an early action to that effect is respectfully requested.

Respectfully submitted,



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PATENT  
Attorney Docket No. 213653  
Client Reference No. OFX042WUS/RF

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Daniele Venturini

Application No. 09/937,941

Filed: January 25, 2002

For: BONE SCREW FOR USE IN  
ORTHOPAEDIC SURGERY

Art Unit: 3732

Examiner: Philogene, Pedro

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**AMENDMENTS TO SPECIFICATION AND CLAIMS  
MADE IN RESPONSE TO OFFICE ACTION DATED NOVEMBER 21, 2002**

*IN THE SPECIFICATION:*

*Amendments to the paragraph beginning at page 5, line 4:*

Accordingly, the core diameter of the threaded portion (i.e. the diameter at the base of the thread) will be 4.5mm at the shank[,] and 2.5mm at the tip. Hence, in this case the ratio between the outside diameter of the threaded portion and the core diameter ranges from 1.43mm at the shank (6mm/4.5mm) (4.0mm/2.5mm) and 1.6 at the tip (4mm/2.5mm).

*IN THE CLAIMS:*

Cancel claim 1 without prejudice.

Rewrite claims 2, 4, 5, 6, 8 and 9 as follows:

*Amendments to claim 2:*

2. (Amended) A bone screw according to [Claim 1] claim 11 characterised in that said shaped bottom land has in cross-section an obtuse angle ( $\beta$ ) of conical convergence towards the longitudinal axis of the screw.

*Amendments to claim 4:*

4. (Amended) A bone screw according to [Claim 1] claim 11,  
[characterised] in which the acute angle of the cross-sectional profile of said teeth is in the range of [that said cusp forms an angle in the] 15° to 30° [range].

*Amendments to claim 5:*

5. (Amended) A bone screw according to [Claim 1] claim 11, characterised in that said constant pitch is of 1.25mm.

*Amendments to claim 6:*

6. (Amended) A bone screw according to [Claim 1] claim 11, characterised in [that the] facing walls of adjacent threads have in cross-section an acute angle ( $\alpha$ ) of conical convergence towards the longitudinal axis of the screw.

*Amendments to claim 8:*

8. (Amended) A bone screw according to [Claim 1] claim 1, characterised in that the threaded portion (5) accounts for [about] one third of the screw length.

*Amendments to claim 9:*

9. (Amended) A bone screw according to [Claim 1] claim 11, characterised in that the height of the thread is three fifths the pitch length.

Add the following new claim 11:

11. (New) A bone screw for use in orthopedic surgery with external fixture fixation devices comprising a head, a shank, and a threaded portion having an outside diameter and a core diameter which tapers toward a tip at an end opposite from the head, said threaded portion having at least one constant pitch section, said threaded portion having threads formed with an acute angle generally triangular cross-sectional profile, said threads being separated from each other by a shaped bottom land having a concave profile defined by two countersloping planes, and said threads having a constant height with the ratio of the outside diameter to said core diameter within a range of 1.43 to 1.60.

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The invention relates to an improved bone screw for use in orthopaedic surgery, in particular with external fracture fixation devices, of the type which comprises ahead (3), a shank (4), and a threaded portion (5) tapering towards a tip (2) at the opposite end from the head (3). Advantageously, the threaded portion (5) has at least one constant pitch section comprising threads (9) which have a triangular cusp-like profile in cross section and are separated from each other by a shaped bottom land with a concave profile (10) defined by two countersloping planes.